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EXAMINER

ROBERTS, LEZAH

ART UNIT PAPER NUMBER

1614

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/791,783 | Applicant(s) YAMAGUCHI ET AL. | |
| | Examiner Lezah W. Roberts | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
 4a) Of the above claim(s) 5-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12 and 13 is/are rejected.
- 7) ☒ Claim(s) 5-11 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>A and B</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims

Claim Objections

Claims 5-11 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claims cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112- Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1) Claims 2-3 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are indefinite insofar as the basis for the percent calculation is not set forth, e.g., percent by weight based on the total weight of the composition, percent by volume based on the volume of the carrier, etc. See Honeywell Intl. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite unless

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the particular method of measurement is recited.) The percent calculation must either be clearly defined within the specification or set forth within the claim.

2) Claims 2-3 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims uses the phrase "having photocatalytic activities" but fails to point out under what circumstance the titanium species have this activity.

3) Claims 1-4 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims uses the term "set", it is indefinite what is meant by the term, i.e. a set of solutions, and if this refers to the packaging of these solution. See for instance "kit".

Claim Rejections - 35 USC § 102-Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Nathoo (US 2003/0103913).

Nathoo teaches dual component whitening compositions comprising a transition metal oxide and hydrogen peroxide. The first and second components remain separate from each other until dispensed for application to teeth. The first component may comprise Pluronic F127 (a thickening agent), water (a carrier) and hydrogen peroxide. The second component comprises titanium dioxide, sodium lauryl sulfate and Tween 20 (which are organic compounds, Tween 20 being a liquid) (see Example 1). In regards to the titanium dioxide having photocatalytic ability, according to Wikipedia, the free encyclopedia, "titanium dioxide is a photocatalyst under ultraviolet light". Therefore, it can be concluded the titanium oxide used in the compositions has photocatalytic activity, as recited by the instant claims. The amount of titanium dioxide incorporated in the second component ranges from 0.1 to 6% by weight and preferably between 0.25 to 4% by weight (page 2, paragraph 0025). The reference anticipates the instant claims insofar as it teaches dual component dental whitening compositions wherein one component comprises peroxide, a carrier and thickening agent, and the second component comprises titanium oxide and an organic solvent.

2) Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Christina-Beck et al. (US 5,766,574).

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Christina-Beck et al. teach dual component tooth whitening dentifrices comprising peroxides. Suitable peroxides used in the invention include hydrogen peroxide. The first component may comprise of peroxide, e.g., hydrogen peroxide, water as a vehicle and a thickening agent (col. 3, lines 6-67). The second component may comprise titanium dioxide and compounds such as glycerin and polyethylene glycol (cols. 7-8, abrasive component table). The titanium used is rutile-type titanium and the concentration incorporated into the composition ranged from 0.5 to 1% by weight, preferably 0.75 to 1.25% by weight. The reference anticipates the instant claims insofar as it teaches dual component dental whitening compositions wherein one component comprises peroxide, a carrier and thickening agent, and the second component comprises titanium oxide and an organic solvent.

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-4 and 12-13 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Montgomery et al. (US 2003/0198605) in view of Morikawa et al. (US 2002/0006865).

Montgomery teaches light activated teeth whitening composition comprising an accelerator and an oxidizing compound. The oxidizing compound may be administered in the same composition or a separate composition from the accelerator. In one embodiment, the tooth whitening composition comprises an oxidizing composition and an accelerator composition that are sequentially applied to a patient's teeth. The accelerator composition may comprise one or both of an alkaline pH adjusting agent, where the pH may be adjusted to an alkaline pH, and a photosensitive agent. Optionally, a performance enhancing adjuvant, such as a buffer, a penetration enhancer, a tooth-desensitizing agent, a fluoride compound, a thickener, or a surfactant, may be included, alone or in combination (paragraph 0036). Useful oxidizing compounds include liquids and gels, preferably containing a peroxide or peroxyacid known in the art. Such oxidizing compounds include, but are not limited to, hydrogen peroxide. Other oxidizing compounds include materials that release hydrogen peroxide upon contact with water (paragraph 0037). When the oxidizing compound is administered in a separate composition from the accelerator, the oxidizing compound may be present in the oxidizing composition in an amount of from about 1.0% to about 40.0% by weight of the oxidizing composition. The indication of a hydrogen peroxide gel

indicates a thickener is in the oxidizing composition as well. Titanium dioxide is useful as a photosensitizer or accelerator agent. Other metal complexes may serve as the accelerator as well. The accelerator used in the disclosed example was used in a concentrations ranging from of 0.01% to 0.50% of the accelerator composition. In one of the compositions, ferric chloride was added in addition to the accelerator agent at a concentration of 0.01% (see table 1), encompassing the amount of metal powder recited in claim 13. The level of thickener, when present, is highly dependent upon the type chosen, but in general is included in the composition at a concentration of from about 0.1% to about 20.0% by weight of the composition, and preferably at a concentration of from about 0.1% to about 5% by weight of the accelerator composition. In addition to a performance enhancing adjuvant, the accelerator composition and/or the oxidizing composition may further include a carrier. Any carrier known in the art may also be included in the oxidizing composition and/or accelerator composition of the present invention. In one embodiment, the accelerator composition is a composition comprising water, glycine, PVP, and potassium hydroxide. PVP is a thickener and adhesion-promoting agent that provides a sufficient thickness of film on the tooth surface in order to deliver a sufficient amount of the alkaline pH adjusting agent to raise the pH higher when the interface forms between the accelerator film and the oxidizing compound (paragraphs 0060-0062). This encompasses the instant claims. The preferred methods of application are methods that allow for the accumulation or concentration of the photosensitizer within the acquired pellicle, enamel, and dentin. This may be accomplished by contacting the stained tooth surface with the

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photosensitizer prior to contacting the same stained tooth surface with the oxidizing composition. In this way, the photosensitizer is able to penetrate into the tooth structure, thus being present at the site of the tooth chromogen(s) prior to contact with the oxidizing composition and prior to exposure to the actinic radiation source. This method encompasses claim 12. In regards to the amount of thickener in the hydrogen peroxide gel, normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). Accordingly it would have been obvious to adjust the amount of thickener to meet the desired viscosity of the composition. The reference differs from the instant claims insofar as it does not disclose titanium dioxide as the preferred photosensitizer or nitrogen doped titanium oxide with added ceramics as the photosensitizers in the accelerator compositions.

Morikawa et al. teaches titanium oxide photocatalyst. The photocatalyst include titanium nitride with the formula Ti-O-N. The Ti-O-N photocatalyst can exert a stable photocatalytic function when irradiated by light in a visible range, and which can be produced easily and at a low cost (paragraph 0008). The photocatalytic substance according to the present invention comprises a photocatalyst material, which operates under visible light, or is activated by visible light, supported on a porous medium. Supporting the photocatalyst material on the porous medium enhances the efficiency of the operation of the photocatalyst material under visible light (paragraph 0009). The photocatalytic substance may include one or more of V, Cr, Mn, Fe, Co, Ni, Cu, Zn, Ru,

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Rh, Pd, Re, Os, Ir, Pt, Mo and Nb, substituting at one or more titanium sites in Ti--O--X, doping between Ti--O--X crystal lattices, doping to crystalline grain boundary of Ti--O--X, or a combination of these methods. The addition of this metal encompasses the metal oxides and metal salts of claim 13. A simultaneous doping of both cationic and anionic species enhances the catalytic activity of the photocatalyst (paragraph 0011). By including such anionic species into an oxide, or by further doping cationic species, a new level is formed in a band gap of the oxide which becomes standard, resulting in a photocatalyst which absorbs visible light (paragraph 0012). The porous medium is preferably formed from ceramics such as alumina, silica, zirconia and titanium oxide; diatomaceous earth, zeolite, sepiolite and activated carbon, or from a composite or mixture of them. Such substances do not readily decompose when in contact with a photocatalytic material, and are therefore preferable for forming a porous medium for supporting the photocatalyst thereon (paragraph 0013). Preferably, the porous medium comprises mesopores. It is further suitable that the porous medium has a honeycomb structure. Such porous medium can maintain a high catalytic activity of the photocatalyst material (paragraph 0014). The honeycomb pattern is similar to a mesh pattern therefore encompassing what is recited in claim 4. It is suitable that one or both of nitrogen (N) and sulfur (S) as anions are doped in atomicity of over 0 and not more than 13% to titanium oxide (TiO_x). The electronic state of a TiO₂ semiconductor is changed by doping N or Ti--O--N, and a new absorption band is formed in a band gap of titanium oxide. As a result, it becomes possible to absorb not only ultraviolet light, but also visible light so that a photocatalytic reaction is observed in response to

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exposure to visible light (paragraph 0031). The presence of nitrogen makes titanium oxide a better photocatalyst. Titanium oxide may have a crystalline structure of anatase and rutile or an amorphous structure, and nitrogen may be doped. When nitrogen is doped, the doped nitrogen and a titanium atom are chemically bonded. Photocatalytic activity in visible light is high when such a chemical bond exists. When the photocatalyst is supported on a silica substrate such as FSM, remarkably enhanced the photocatalytic function. This is because FSM has very small projections and depression on its surface (paragraph 0048). The same effects were also observed when materials such as Ti--O--N--Fe, Ti--O--N--V, Ti--O--N--Cu and Ti--O--N--Co were used as the photocatalyst material (0049). The catalytic function of photocatalytic material also tends to promote decomposition of organic substances. The reference differs from the instant claims insofar as it does not disclose using the photocatalyst of the present invention in compositions for whitening teeth.

It would have been obvious to one of ordinary skill in the art to have used the photocatalyst compositions comprising additional metal oxides and nitrogen doped titanium oxide in the whitening compositions of the primary reference motivated by the desire to enhance photocatalytic activity and to activate the photocatalyst with visible light at higher wavelengths as disclosed by the secondary reference.

2) Claims 1-2 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery et al. (US 6,162,055) in view of Fujishima (US 6,387,844).

Montgomery teaches light activated teeth whitening composition comprising an accelerator and an oxidizing compound. The oxidizing compound may be administered in the same composition or a separate composition from the accelerator. Various modes of application of the inventive tooth bleaching compositions are effective, although methods that allow for the accumulation or concentration of the photosensitizer within the acquired pellicle, enamel, and dentin are most preferred. This is best accomplished by contacting the stained tooth surface with the photosensitizer prior to contacting the same stained tooth surface with the oxidizing composition. In this way, the photosensitizer is able to penetrate into the tooth structure, thus being present at the site of the tooth chromogen(s) prior to contact with the oxidizing composition and prior to exposure to the actinic radiation source (col. 6, lines 58-67). This requires the accelerator and oxidizing agent to be packaged in separate compositions as recited by the instant claims. The accelerators used in the compositions include titanium dioxide (col. 7, lines 11-13). Useful oxidizing compounds include liquids and gels, preferably containing a peroxide or peroxyacid known in the art. Such oxidizing compounds include, but are not limited to, hydrogen peroxide (col. 8, lines 57-60). An example a suitable peroxide containing composition is a 6% hydrogen peroxide gel with a pH of about 7.0 that has been thickened to approximately 100,000 cps with neutralized carboxypolymethylene (col. 9, lines 26-30). It can be concluded the composition comprises water by the disclosed prior art within the reference and the water-soluble thickener disclosed that creates the gel. The one part composition comprises water, 35% hydrogen peroxide (in water), carbopol and an accelerator. If this composition was

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separated, it can be concluded the peroxide would make up about at least 30 % of the individual composition (see ingredient table). There for the accelerator would have made up at least 2% of the accelerator composition. The compositions also comprise a transparent carrier, which encompasses the instant claims. The reference differs from the instant claims insofar as it did not disclose the accelerator composition comprises an organic solvent; the preferred accelerator was titanium dioxide, nitrogen doped titanium oxide or titanium oxinitride; or a metal salt or powder being incorporated into the composition.

Fujishima et al. teach the preparation of photocatalytic titanium dioxide films on a substrate. Dissolving the titanium dioxide powder in a binder, i.e acetylacetone, made the films, which were then placed on a substrate (col. 2, lines 1-5). According Wikipedia, the online encyclopedia, titanium dioxide has limited solubility in water, therefore it can be concluded an organic solvent is needed to dissolve the powder. The reference differs from the instant claims insofar as it does not disclose using the photocatalytic titanium dioxide films in a teeth bleaching composition.

It would be obvious to one of ordinary skill in the art to have mixed the titanium dioxide with an organic solvent to incorporate into the compositions and methods of the primary reference motivated by the desire to make application of the titanium dioxide easier by using a solution or film as oppose to powder or slurry.

3) Claims 1-4 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery et al. (US 6,162,055) in view of Fujishima (US

6,387,844) as applied to claims 1- and 12 above, and further in view of Morikawa et al. (US 2002/0006865).

The primary and secondary references are discussed above. The references differ from the instant claims insofar as they do not disclose the compositions comprising an addition metal component; or a nitrogen doped titanium oxide or a titanium oxinitride.

The tertiary reference is discussed above. Several of the titanium metals in Ti-O-N are doped with addition metal, thereby encompassing the addition metal recited in claim 13. The reference differs from the instant claims insofar as it does not disclose using the photocatalyst of the present invention in compositions for whitening teeth.

It would have been obvious to one of ordinary skill in the art to have used the titanium oxide photocatalysts the compositions of the combined teachings of the primary and secondary references motivated by the desire to enhance photocatalytic activity, thereby enhancing bleaching results and to activate the photocatalyst with visible light at higher wavelengths as disclosed by the tertiary reference.

In regards to the amount of additional metal oxide, salt or powder in the composition recited in claim 13, it would have been obvious that the concentration of the additional metal is less than that of the titanium oxide component, which would have been at least 2% taken with the combined teachings of the primary and secondary references therefore falling in the range of .0001% to 10% as recited in claim 13.

Obvious-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 12-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/644808 in view of Montgomery (US 2003/0198605). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are coextensive because they read on a bleaching agent for the teeth, which comprise titanium oxide and hydrogen peroxide. The instant claims differ from the copending claims insofar as the copending claims recite a one step method and one part composition and the instant claims recite a two-step method and two part composition.

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The secondary reference discloses compositions with a photocatalyst and oxidizing agent may be applied to the teeth at the same time in one composition and they may also be separated and each component applied sequentially.

It would have been obvious to one of ordinary skill in the art to used both a one step and a two step method when applying a bleaching agent to the teeth because the composition may be applied either way.

This is a provisional obviousness-type double patenting rejection.

Claims 1-4 and 12-13 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lezah Roberts
Patent Examiner
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A handwritten signature in black ink, appearing to read "Lezah Roberts", followed by a long horizontal flourish line.